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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jocelyne Franchi

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NATH & ASSOCIATES

112 South West Street

Alexandria, VA 22314

EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/506,407	Applicant(s) FRANCHI ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-84 is/are pending in the application.
- 4a) Of the above claim(s) 36-39, 45-66, 70-73 and 80-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-35, 40-44, 67-69, 74-79 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on April 28, 2006.

Claims 31-84 are pending in the application, with claims 36-39, 45-66, 70-73 and 80-83 being withdrawn as drawn to a non-elected invention. Accordingly, claims 31-35, 40-44, 67-69, 74-79 and 84 are being examined on the merits herein.

The objection to claim 44 is being withdrawn in view of the amendment to the claim.

The rejection of claims 31-32, 34 and 84 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,578,641 to Jackson et al. is being withdrawn in view of Applicant's amendments to the claims. In particular, Jackson et al. does not specifically teach the step of "selecting a part or parts of the body in need of slimming effect," as recited in claim 31, and thus does not anticipate the claims.

The rejection of claims 31-34 and 84 under 35 U.S.C. 102(b) as being anticipated by WO 00/53568 to Streekstra et al. is being withdrawn in view of Applicant's amendments to the claims. In particular, Streekstra et al. does not specifically teach the step of "selecting a part or parts of the body in need of slimming effect," as recited in claim 31, and thus does not anticipate the claims.

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The rejection of claims 31-32, 34 and 84 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,372,236 to Park et al. is being withdrawn in view of Applicant's amendments to the claims. In particular, Park et al. does not specifically teach the step of "selecting a part or parts of the body in need of slimming effect," as recited in claim 31, and thus does not anticipate the claims.

The claims are rejected as follows.

Claim Objections

Claim 1 is objected to because of a grammatical error. In particular, the claim recites a method "comprising selecting a part or parts of the body in need of slimming effect; the application on the part or parts of the body in need of slimming effect of an effective amount of a cosmetic composition" The Examiner respectfully suggests amending the claim to recite the method comprising "selecting a part or parts of the body in need of slimming effect; and the application on the part or parts of the body in need of slimming effect of an effective amount of a cosmetic composition ..." (underline added.)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-35, 41-44 and 84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, specification as originally filed does not provide sufficient support for the step of "selecting a part or parts of the body in need of slimming effect," as recited for example in claim 31. The specification as originally filed discloses that phytosphingosine can be used as a slimming agent and for reducing subcutaneous fat (see page 4, lines 5-30, in particular), but does not teach the specific step of selecting a part or parts of the body in need of slimming effect, as recited in the claims. Accordingly, the claims as instantly amended recite new matter and are rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, as applied to claims 31-32, 34 and 84 above, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Jackson et al. also does not specifically teach providing a composition with a lipolytic agent, as recited in claims 35, 40-42, 67, 69 and 74-76. However, Jackson et

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al. does teach that further cosmetic adjuvants can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al. and applying to skin in need thereof, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

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individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Bombardelli et al. teaches that a composition with ingredients including an adenylate cyclase enzyme stimulator (activating agent) can improve the early aging of skin. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

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prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 74, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claim 67 above. Regarding claim 75, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 76, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as applied to claims 67, 69 and 74-76 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Jackson et al and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, to provide an antiaging effect, and also teach that the same parts of the body in need of an anti-aging effect can be those in need of a slimming effect. Jackson et al. and Bombardelli et al. also teach that the composition can comprise an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 68.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

Claim 77 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 67, 69 and 74-76 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claim 77.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition. Accordingly, claim 77 is obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 101(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. is applied as discussed above, and teaches a method for application to the skin of a formulation comprising phytosphingosine. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 67, 69 and 74-79.

Andre et al. teaches that an extract of *Tephrosia purpurea* provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of

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Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Andre et al. teaches that a composition with an extract that is an adenylate cyclase enzyme stimulator (activating agent) can provide anti-aging effects. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase activating extract of Andre et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats

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aging of skin such as skin wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Andre et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 74, Andre et al. teaches that the extract is an adenylate cyclase enzyme activator.

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 78-79, Andre et al. teaches that the extract can be from *Tephrosia purpurea*, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claim 79. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 31-32, 34-35, 40-42 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as evidenced by U.S. Patent No. 4,885,157 to Fiaschetti et al, issued December 5, 1989.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Jackson et al. does not specifically teach selecting a part or parts of the body in need of slimming effect, as recited in claim 31.

Bombardelli et al. teaches that skin early aging effects face and neck skin (see column 3, lines 1-12, in particular.)

Fiaschetti et al. teaches a composition capable of the dissolution of fat pockets (see abstract, in particular), and teaches treating individuals having fatty pockets under the eyes i.e. on the face.) Thus, Fiaschetti et al. teaches that the parts of the face are in need of slimming effect, and thus teaches that selecting a part or parts of the body in need of slimming effect can include selecting parts of the face.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to apply the composition of Jackson et al. to parts of the face, as taught by Bombardelli et al, and thus to select a part of the body in need of slimming effect, as evidenced by Fiaschetti et al, because Jackson et al. teaches that the composition can be applied to skin provide an anti-aging effect, and Bombardelli et al. teaches that face skin is susceptible to early aging. Thus, one of ordinary skill in art would have been motivated to apply the composition of Jackson et al. to parts of the face with the expectation of providing anti-aging effects. Accordingly, claim 31 is obvious over Jackson et al. and Bombardelli et al. as evidenced by Fiaschetti et al.

It is noted that claim 31 is directed to a method that obtains a slimming effect on parts of the body in need thereof by applying the phytosphingosine. However, as the teachings of Jackson et al. and Bombardelli et al. as evidenced by Fiaschetti et al. render the claimed composition and claimed steps obvious, the property of such a claimed composition is also rendered obvious by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior

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art teaches or renders obvious the cosmetic composition, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

It is furthermore noted that claim 32 is directed to a method that is intended for reducing subcutaneous excess fat by applying the phytosphingosine. However, as the teachings of Jackson et al. and Bombardelli et al. as evidenced by Fiaschetti et al. render obvious the claimed composition and the claimed method steps, the property of such a claimed composition is also taught or rendered obvious by the prior art, since the properties, namely the reduction of subcutaneous fat, are inseparable from its composition. Therefore, if the prior art teaches or renders obvious the cosmetic composition, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Regarding claim 34, Jackson et al. exemplifies a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim.

Regarding claim 84, it is noted that the claim recites that the active agent is present in the composition in an effective amount for stimulating the synthesis of leptin by adipocytes. It is furthermore noted that Jackson et al. exemplifies providing 0.1% of phytosphingosine. Thus, as the teachings of Jackson et al. render obvious the claimed composition, the property of such a claimed composition is also rendered obvious by the prior art, since the properties, namely stimulating the synthesis of leptin by adipocytes, are inseparable from its composition. Therefore, if the prior art teaches or renders obvious the cosmetic composition, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Jackson et al. also does not specifically teach providing a composition with a lipolytic agent, as recited in claims 35 and 40-42. However, Jackson et al. does teach that further cosmetic adjuvants can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Fiaschetti et al. has been discussed above, and teaches that parts of the face are those that are in need of a slimming effect, as discussed above.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, and apply to parts of the face (parts of the body in need of slimming effect) because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging, such as in the face, which is a part of the body that can be in need of slimming effect, as evidenced by Fiaschetti et al.. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al. and applying to skin in need thereof, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding claim 40, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claims 35 and 67 above. Regarding claim 41, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 42, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as evidenced by U.S. Patent No. 4,885,157 to Fiaschetti et al, issued December 5, 1989, as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Jackson et al and Bombardelli et al, as evidenced by Fiachetti et al, are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, to provide an antiaging effect, and also teach that the same parts of the body in need of an anti-aging effect can be those in need of a slimming effect. Jackson et al. and Bombardelli et al. also teach that the composition can comprise an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. does not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 33.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the

expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as evidenced by U.S. Patent No. 4,885,157 to Fiaschetti et al, issued December 5, 1989, as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. and Bombardelli et al. as evidenced by Fiaschetti et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin, including skin in need of a slimming effect. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al, Bombardelli et al. and Fiaschetti et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claim 43.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, as evidenced by Fiaschetti et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition. Accordingly, claim 43 is obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

Jackson et al. and Bomardelli et al, as evidenced by Fiaschetti et al. also do not specifically teach providing an adenylate cyclase activating agent that is an extract of the plant *Tephoria purpurea*, as recited in claim 44.

Andre et al. teaches that an extract of *Tephrosia purpurea* provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of Jackson et al and Bombardelli et al, as evidenced by Fiaschetti et al, because Jackson et al. and Bombardelli et al. teach applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and Bombardelli and applying to skin, including skin that is also in need of a slimming effect, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding claim 44, Andre et al. teaches that the extract can be from Tephrosia purpurea, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claim 44.

Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Response to Arguments

Applicant's arguments with respect to claims 31-35, 40-44 and 84 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments regarding the rejections of claims 67-69 and 74-79 have been fully considered but they are not persuasive. In particular, Applicant's argue that the composition claims are not obvious over the teachings of Jackson et al. and Bombardelli et al., as well as Jackson in view of Andre, because the references do not specifically teach the selection of a part of the body needing a slimming effect. The

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Examiner notes that the features upon which applicant relies (i.e., selecting a body part in need of slimming effect) are not recited in the rejected composition claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC


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